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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NEW YORK, NY 10022

EXAMINER

SALMON, KATHERINE D

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/718,391	Applicant(s) ENGELHARDT ET AL.	
	Examiner Katherine Salmon	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-103 is/are rejected.
- 7) ☒ Claim(s) 94 and 102 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/10/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

DETAILED ACTION

1. Claims 1-90 are canceled.
2. An action on the merits of Claims 91-103 is set forth below.

Priority

3. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not

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extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

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Addition of a paragraph in the beginning of the specification describing the relationship of the claimed priority is required.

Abstract

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words and uses the phrase "disclose in this invention". Correction is required. See MPEP

§ 608.01(b).

Specification

5. The disclosure is objected to because of the following: at p. 6, 8, 10, 12, 14, and 17, the specification contains a drawing. This should not be included in the text of the specification but should be submitted as a separate figure, including a description of the figure in the specification. See 37 CFR 1.58. Care should be taken not to introduce new matter in the description of the figures. Appropriate correction is required.

Claim Objections

6. Claims 94 and 102 objected to because of the following informalities: DNA:RNA should be written DNA:RNA. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 91-95 and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuster et al. (US Patent 5,169,766 December 8, 1992)

Schuster et al. teaches a method of amplifying a nucleic acid molecule. With regard to Claim 91, Schuster et al. teaches providing a DNA target and mixing the target with nucleoside triphosphates (Figure 1 Column 7, lines 60-65). Schuster et al. teaches the use of primers which are chemically modified by blocking the 3' terminus using a 3' terminal nucleotide lacking a 3' hydroxyl group (Column 11 lines 60-64). Schuster et al.

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teaches conditions or agents (nucleic acid producing catalysts) which increase amplification are present (Column 7, lines 50-55). Schuster et al. teaches that the assay mixture has a sufficient quantity of cofactors to support the degree of amplification desired (Column 7, lines 60-65). Schuster et al. teaches isostatic conditions, such as, the use of Tris base (pH stabilizer) in the amplification reactions, stable temperature of 37°C for 3 hours, and with a specific number of molecules of RNA (Column 13, lines 40-52). With regard to Claims 92 and 93, Schuster et al. teaches the use of Rnase H to remove RNA from the cDNA (Column 8, lines 7-10). Schuster et al. teaches an mRNA promoter (primer) which is used to extend and make ssRNA (Figure 3). Schuster et al. teaches another primer (DNA) is annealed to the ssRNA and cDNA is copied (Figure 3). Schuster et al. teaches the ssRNA (which is the extended promoter) is destroyed by Rnase H. Further, any primers which are in the solution but did not primer to the original ssDNA would be destroyed by Rnase H, therefore allowing for a reaction solution with only the cDNA that allows the completion of another cycle and the production of another cDNA strand identical to the ssDNA template. With regard to Claim 94, Schuster et al. teaches the primers can be DNA or RNA (Column 5 lines 35-38 and 55-60). With regard to Claim 95, Schuster et al. teaches the use of primers which are chemically modified by blocking the 3' terminus using a 3' terminal nucleotide lacking a 3' hydroxyl group (Column 11 lines 60-64). With regard to Claim 98, Schuster et al. teaches a promoter (primer) in which at least 1 nucleotide is noncomplementary (Fig 2 5th step).

8. Claims 91-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Kacian et al. (US Patent 5554516 September 10, 1996).

In the event that priority to prefiled applications is perfected then this rejection would be given under 35 U.S.C. 102(e).

Kacian et al. teaches a method of amplifying a target nucleic acid sequence (Abstract). With regard to Claim 91, Kacian et al. teaches a method of incubating a promoter-primer and a target sequence in DNA priming and nucleic acid synthesizing conditions (ribonucleotide triphosphates and deoxyribonucleotide triphosphates) for a period of time to many multiple copies of the target sequence (Column 10 lines 23-33). Kacian et al. teaches using a DNA polymerase (nucleic acid producing catalyst) (Column 10 line 59). Kacian et al. teaches that the reaction takes place under conditions that are substantially isothermal and include substantially constant ionic strength and pH, i.e. isostatic conditions (Column 10 lines 37-45). With regard to Claims 92-93, Kacian et al. teaches that generation of target sequence is done using Rnase H (Column 4 lines 65-67 and Column 5 lines 1-5). Kacian et al. teaches the promoter-primer may be altered with ribonucleotides (Column 9, line 15). Therefore Kacian et al. teaches a reaction in which Rnase H is in the presence of a RNA-DNA hybrid (DNA target with a promoter with ribonucleotides), it is inherent that the Rnase H will denature the ribonucleotide promoter and thereby release the DNA target from the promoter. With regard to Claim 94, Kacian et al. teaches the use of DNA as a primer sequence (Column 6 lines 18-25). Kacian et al. teaches that this sequence may have modifications such as dideoxynucleotide residues that have been modified such as

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phosphorothioates (chemically) (Column 9, lines 14-16). With regard to Claim 95, Kacian et al. teaches the 3' end of the promoter-primer may be modified (Column 7, line 6). With regard to Claim 96, Kacian et al. teaches that one modification can be the addition of a phosphorothioate (sulphur heteroatom) (Column 9 lines 17). With regard to Claim 97, Kacian et al. teaches that promoter-primer can include the addition of 3'2' dideoxynucleotide residues modified with phosphorothioates (Column 9 lines 15-17). With regard to Claim 98, Kacian et al. teaches a promoter primer which has at least one nucleotide that is noncomplementary (Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (US Patent 5,169,766 December 8, 1992) in view of Skerra (Nucleic Acids Research 1992 Vol. 20 p. 3551).

Schuster et al. teaches a method of amplifying a nucleic acid molecule. Schuster et al. teaches providing a DNA target and mixing the target with nucleoside triphosphates (Figure 1 Column 7, lines 60-65). Schuster et al. teaches the use of primers which are chemically modified by blocking the 3' terminus using a 3' terminal nucleotide lacking a 3' hydroxyl group (Column 11 lines 60-64). Schuster et al. teaches conditions or agents which increase amplification are present (Column 7, lines 50-55). Schuster et al. teaches that the assay mixture has a sufficient quantity of cofactors to support the degree of amplification desired (Column 7, lines 60-65). Schuster et al. teaches the use of Rnase H to remove RNA from the cDNA (Column 8, lines 7-10).

Schuster et al., however, does not teach primers modified by heteroatoms comprised of nitrogen or sulfur and chemically modified primers comprised of nucleoside triphosphates.

Skerra teaches a method of using phosphorothioate primers in an amplification method (Abstract). With regard to Claims 96-97, Skerra teaches the modification of primers by the addition of a single phosphorothioate bond (heteroatom of sulfur) at the first 3' terminal internucleotide linkage during synthesis of the oligodeoxynucleotide (p. 3552 1st column last paragraph). Skerra teaches that the phosphorothiate bond is much

less favored substrate to nuclease activity than the naturally occurring phosphodiester bond (P. 3552 1st column last sentence and 2nd column 1st sentence).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schuster et al., to use the phosphorothioate primers as taught by Skerra. The ordinary artisan would have been motivated to modify the method of Schuster et al, because Skerra teaches the use of phosphorothioate primers would avoid the lower PCR yield and non-specific side products resulting from 3' terminal editing of the primer molecule by protecting the oligodeoxynucleotide from a 3' terminal exonucleolytic attack (p. 3553 2nd column last paragraph).

11. Claims 99-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (US Patent 5,169,766 December 8, 1992) in view of Cerretti et al. (US Patent 5,317,087 May 31, 1994).

Schuster et al. teaches a method of amplifying a nucleic acid molecule. With regard to Claim 99, Schuster et al. teaches providing a DNA target and mixing the target with nucleoside triphosphates (Figure 1 Column 7, lines 60-65). Schuster et al. teaches conditions or agents which increase amplification are present (Column 7, lines 50-55). Schuster et al. teaches that the assay mixture has a sufficient quantity of cofactors to support the degree of amplification desired (Column 7, lines 60-65). With regard to Claims 100 and 101, Schuster et al. teaches the use of Rnase H to remove RNA from the cDNA (Column 8, lines 7-10). With regard to Claim 102, Schuster et al. teaches the

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primers can be DNA or RNA (Column 5 lines 35-38 and 55-60). With regard to Claim 103, Schuster et al. teaches a promoter (primer) in which at least 1 nucleotide is noncomplementary (Fig 2 5th step).

Schuster et al., however, does not teach primer hybridization in which at least one loop structure is formed.

Cerretti et al. teaches that a library of cDNA can be prepared by using hairpin loop primers (Column 11 lines 10-26). Cerretti et al. teaches the mRNA primer is hybridized to a first cDNA strand (Column 11 lines 10-26). Cerretti et al. teaches that this results in a "hairpin" loop at the 3' end of the initial cDNA strand that serves as an integral primer for the second DNA strand (Column 11 lines 10-26). Cerretti et al. teaches that the second cDNA strand is synthesized using a DNA polymerase and the hairpin loop is cleaved to produce double stranded cDNA molecules (Column 11 lines 10-26).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schuster et al. to use the hairpin loop primer as taught by Cerretti et al. The ordinary artisan would have been motivated to modify the method of Schuster et al. because Cerretti et al. teaches a method of using hairpin loops to copy small cDNA fractions from a large cDNA template (Column 11 lines 10-26). The ordinary artisan would want to use hairpin loops as a way to prepare a library of double-stranded cDNA and would want to cleave the mRNA primer from the target cDNA in order to keep using the original long strand of cDNA. The ordinary artisan would therefore be able to produce multiple copies at multiple

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positions of the target cDNA strand by annealing a mRNA primer, copying a fragment of cDNA with a hairpin loop, removing the mRNA primer, and adding another mRNA primer somewhere else on the target DNA.

12. Claims 99-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kacian et al. (US Patent 5554516 September 10, 1996) in view of Cerretti et al. (US Patent 5,317,087 May 31, 1994).

Kacian et al. teaches a method of amplifying a target nucleic acid sequence (Abstract). With regard to Claim 99, Kacian et al. teaches a method of incubating a promoter-primer and a target sequence in DNA priming and nucleic acid synthesizing conditions (ribonucleotide triphosphates and deoxyribonucleotide triphosphates) for a period of time to many multiple copies of the target sequence (Column 10 lines 23-33). Kacian et al. teaches using a DNA polymerase (nucleic acid producing catalyst (Column 10 line 59). Kacian et al. teaches that the reaction takes place under conditions that are substantially isothermal and include substantially constant ionic strength and pH (Column 10 lines 37-40). With regard to Claims 100-101, Kacian et al. teaches that generation of target sequence is done using Rnase H (Column 4 lines 65-67 and Column 5 lines 1-5). With regard to Claim 102, Kacian et al. teaches the use of DNA as a primer sequence (Column 6 lines 18-25). With regard to Claim 103, Kacian et al. teaches a promoter primer which has at least one nucleotide that is noncomplementary (Figure 1).

Kacian et al., however, does not teach primer hybridization in which at least one loop structure is formed.

Cerretti et al. teaches that a library of cDNA can be prepared by using hairpin loop primers (Column 11 lines 10-26). Cerretti et al. teaches the mRNA primer is hybridized to a first cDNA strand (Column 11 lines 10-26). Cerretti et al. teaches that this results in a "hairpin" loop at the 3' end of the initial cDNA strand that serves as an integral primer for the second DNA strand (Column 11 lines 10-26). Cerretti et al. teaches that the second cDNA strand is synthesized using a DNA polymerase and the hairpin loop is cleaved to produce double stranded cDNA molecules (Column 11 lines 10-26).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kacian et al. to use the hairpin loop primer as taught by Cerretti et al. The ordinary artisan would have been motivated to modify the method of Kacian et al. because Cerretti et al. teaches a method of using hairpin loops to copy small cDNA fractions from a large cDNA template (Column 11 lines 10-26). The ordinary artisan would want to use hairpin loops as a way to prepare a library of double-stranded cDNA and would want to cleave the mRNA primer from the target cDNA in order to keep using the original long strand of cDNA. The ordinary artisan would therefore be able to produce multiple copies at multiple positions of the target cDNA strand by annealing a mRNA primer, copying a fragment of cDNA with a hairpin loop, removing the mRNA primer, and adding another mRNA primer somewhere else on the target DNA.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 91-99 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 91-101 of copending Application No. 10/713183. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 91-99 of the instant application describes the same method steps as Claim 91-101 of application 10/713183. Both applications are drawn to a method of producing copies of a specific nucleic acid by providing a nucleic acid sample, contacting it with unmodified nucleic acid precursors and modified RNA primers. Both applications use a catalyst. Both applications modify

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primers using heteroatoms comprising nitrogen or sulfur. Both applications claims are drawn to primers, which comprise about 1 to about 200 noncomplementary nucleotide or nucleotide analogs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claims are allowable over the cited prior art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon 5/12/2005

Katherine Salmon
Examiner
Art Unit 1634

J. Goldberg
JEANINE A. GOLDBERG
PRIMARY EXAMINER
5/12/06